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Health Articles, courtesy of Enzymatic Therapy

Understanding Excipients

Enzymatic Therapy (*as other companies do*) uses excipients, those "extra" ingredients in products, for very good reason. They serve as lubricants, disintegran binders, adsorbents, and glidants for four key purposes.

Excipients

- Help transport key ingredients to the site in the body where they can be adsorb
- Prevent the ingredients from being released too early in the assimilation proces
- Help the tablet or capsule to disintegrate into particles small enough to reach th bloodstream quickly.
- Protect the product's stability so it will be at maximum effectiveness at the time use.[1]

Enzymatic Therapy uses excipients from **natural sources** whenever possible, and only the minimum amount of excipient necessary to ensure an effective product

All excipients used in their products (and in all food, drugs, or nutritional supplements sold in the United States) are approved by the Food and Drug Administration, as mandated by Congress in the United States Code of Federal Regulations.[2] Enzymatic Therapy also adheres to the United States Pharmacopeia (USP), National Formulary, standards for identity, strength, and labeling for excipients.

REFERENCES:

1. Pharmaceutical excipients. International Pharmaceutical Excipients Council of the Americas. Available at: www.ipecamericas.org/public/faqs.html. Accessed Aug. 16, 1999.
2. Substances Generally Recognized as Safe. United States Code of Federal Regulations. Title 21, Part 182-186. Available at: www/access.gpo.gov/nara/cfr/waisidx_99/21cfrv3_99.html. Accessed Aug. 17, 1999.

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EXCIPIENT	FUNCTION	SOURCE
Magnesium Stearate	This lubricant is used for powder that tends to adhere to processing equipment, and in some cases, for powder that does not flow well.	Produced by combining magnesiu and stearic acid.
Stearic Acid	A lubricant and binder, similar to magnesium stearate.	Cottonseed and othe vegetable oils.
Colloidal silicon dioxide	An **adsorbent**, glidant, and disintegrant, colloidal silicon dioxide has a small particle size and a large specific surface area. This gives the material desirable flow characteristics, and makes it suitable for a number of uses. It can aid in disintegration or help powders that do not flow well.	Very small particles the mineral silica.
Cellulose gum	This material is stable, but hygroscopic, thus acting as a super disintegrant. **Cellulose** gum will swell to four to eight times its original volume on contact with water. The swelling of the material breaks the capsule/tablet apart, thus allowing the other key components (the ones that are required to dissolve) to be exposed to the solution and dissolve faster than without the **cellulose** gum.	Prepared from **cellulose** obtained fr wood or cotton.
Microcrystalline cellulose	This material is inert and naturally occurring. It functions as a diluent, **adsorbent**, lubricant, and disintegrant. It is widely used as a diluent in tablet and capsule formulations. In higher quantities it has some lubricant and disintegrant properties. This excipient is highly compactable in dry form, which makes it useful for tableting.	Fibrous plant materi such as wood.
Vanillin	This sweet-smelling material from vanilla masks the odor of some of the other ingredients in certain products.	Naturally occurring i many essential oils.
Titanium Dioxide	This material is used to give white color to foods, cosmetics, and topical and oral preparations.	Naturally occurring i various mineral sources.

DEFINITIONS:

Adsorbent: A substance that leads readily to adsorption, which is adhesion to the surface of a solid.

Diluent: Dilutes the substance or solution to which it is added.

Disintegrant: Causes the constituents of a substance to break apart.

Excipient: Inert substance added to a tablet, capsule, or liquid to make it easier to administer. An excipient is chosen based on the characteristics of the compound in product and how it's going to be processed (as a tablet, capsule, or liquid).

Glidant: Reduces interparticle friction and also acts as a moisture scavenger. The properties help with product flowability.

Hygroscopic: Readily absorbs moisture.

Lubricant: Agent that reduces friction between substances that rub against each other (as in between particles and the surface of the processing equipment).

Definitions are based on information taken from the Handbook of Pharmaceutical Excipients, *2nd edition (Wade A and Weller PJ, eds. Washington, DC: American Pharmaceutical Association, 1994)*

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Frequently Asked Questions

Drs. Rodriguez and Christensen

Monday - Wednesday - Friday 11:00 - 11:50 a.m.
Room: PHAR 305
Winter 2002

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- **I read the caption on pg 102 (article on geomatrix in the packet). It appears there is an inner CORE not layer that is SURROUNDED by the outer slow-hydrating matrix. It seems that the tab can NOT be cut or chewed. In class it was said that it could be cut. Cutting seems to expose the fast hydrating core and cause moderate dumping.**

  I apologize for the description in the paper and understand the reason for confusion. The authors should have not used the term "surrounded" or "inner core". The inner tablet is NOT ENTIRELY surrounded with the slow hydrating layer, only the TOP and BOTTOM of the tablet is protecting the inner matrix core from rapid hydration. The inner core (layer) is only hydrated from the sides of the tablet because there is no coating to slow the hydration down. This is clearly visible in the actual formulation Dilacor XR The tablet can be cut but not chewed. Also, it is always possible to have mild to moderate dose dumping with matrix tablets. I will cover this issue in Friday's lecture.

- **Will we be expected to recall brand name or generic examples of specific drug forms and delivery systems?**

  I would like for you to know the BRAND name because it is this form that is using the patented drug release technology. For example, Procardia XL (nifidipine) utilizes the osmotic pump technology while both Adalat CC and Procardia have distinct drug

release characteristics.

- **What is Osmotic Diarrhea?**

  Osmotic Diarrhea is produced by ingesting poorly absorbable solutes. This occurs in carbohydrate malabsorptive diseases or may be induced by ingesting Mg Citrate (both ions are poorly absorbed). The latter is packaged as a 300 ml solution containing ~17.5 g of Mg Citrate. Its osmotic strength about 550 mOsM. A single 300 ml dose is sufficient to keep one in the close vicinity of a bathroom, while two doses spaced a few hours apart will clean the lower GI tract well enough to permit a colonoscopy exam. The effect of this hypertonic solution is to cause both salt (NaCl) and water to flow from extracellular fluid (ECF) to the intestinal lumen. To better show you how a non-absorbed solute affects the flow of salt and water across the intestine.

- **What is the property of microcrystalline celulose that help granules to fall apart during the process of disintegration?**

  Microcrystalline cellulose absorbs water and swells while separating back into the individual particles which were originally compressed. Thus, the tablet falls apart when the MCC particles no longer hold together.

- **Starch is most commonly used as binders, disintegrant. What else starch can be used?**

  These are the most common uses. In some sustained release products, starch is added wet in relatively large amounts and still acts as a binder, but in this case, it binds the ingredients together for so long that the tablet only slowly erodes and releases drug slowly. This issue will be covered again during the section about sustained release formulations.

- **Why kaolin is used for diarrhea treatment? and How does it work?**

  Kaolin adsorbs toxic amines produced by bacteria in the intestine, thus preventing the toxic amines from irritating the intestinal cells. Also, kaolin is a clay that adsorbs water, and thus helps make the feces more solid and less runny, i.e., less diarrhea in appearance.

- **I would like to do some more reading about talc,calcium PO4,but I could not find them in the text. Would you please tell me where I can find them?**

  The library should have a thick text called "Remmington's Pharmaceutical Sciences. This is an excellent source of more information about individual pharmaceutical excipients.

- **What are the characteristics of Lactose and Microcrystalline Cellulose?**

  Lactose displays good solubility and compatibility with other drugs.

  Microcrystalline Cellulose also displays good compatibility with other drugs as well

as being compactable and uniform.

- **What is the maximum dose of a tablet for swallow?**

  1.1 ml is accepted as the maximum volume of solid a person can swallow (of course some people can swallow more and some less), and that means about 1.3 gm is the maximum acceptable tablet weight since the compressed tablet can have a density greater than 1.0. In reality, most commercial products intended to be swallowed whole weigh 1.0 grams or less (usually about 400-600 mg).

- **What is the property of microcrystalline celulose that help granules to fall apart during the process of disintegration?**

  MCC absorbs water and expands, and the expansion forces the tablets granules apart.

- **Starch is most commonly used as binders, disintegrant. What else starch can be used?**

  These are the only "common" uses that we will consider in this class. Other uses include absorbent (rarely), and filler but also rarely.

- **I would like to do some more reading about talc,calcium PO4,but I could not find them in the text. Would you please tell me where I can find them?**

  See earlier reference to Remington's Pharmaceutical Sciences

- **How does PVP act as a binder and a disintegrant?**

  The mechanism is the same as for starch. Do you know that mechanism, or is this your question?

- **Is buccal also under soluble tablet?**

  Buccal tablets are soluble but are usually slowly soluble. This is somewhat confusing since soluble tablets are expected to be rapidly soluble, and sublingual and hypodermic tablets are rapidly soluble while buccal tablets dissolve more slowly, over 1/2-3 hours. Buccal tablets usually do not contain flavors as we do not want salivation to be stimulated and we do not want the drug to be swallowed.

- **What is the advantage of using effervescent tablet?**

  Effervescent tablets allow a solid dosage form to be prepared and delivered, and then the patient dissolves the product in water so a liquid dosage form is taken by the patient. The drug will be absorbed quickly because it is already in solution at the time of administration. And, the carbon dioxide is a weak local anesthetic for the back of the mouth. Liquids are much easier to swallow than tablets.

- **Can you please clarify the "bounce back" effect?**

  The "bounce back" term refers to the process where the pyloric sphincter closes and the stomach squeezes the tablet back up into the stomach and will not allow the tablet

to pass into the intestine. This is thought to occur because the stomach is designed to not allow large chunks of food to pass into the intestine. Only small, partially digested food is usually passed into the intestine. However, once the stomach is nearly empty, then the sphincter relaxes and a large contraction of the stomach occurs and whatever is in the stomach will be swept into the intestine. Most things small enough to be swallowed will be moved into the intestine by this "housekeeper" wave.

- **How do you distinguish between binder and adsorbent that being added in the process (for ex. starch can be use for both)?**

  Starch will not be an **adsorbent** in any tablets we consider. That is a rare use.

- **How do people take triturates tablet? (does it need to be dissove in solution first?)**

  Tablet triturates are not used much any more, and the most common use is sublingual. If they are hypodermic tablet triturates, then they must be dissolved for injection.

- **Why would large therapeutic range is preferred over narrow range for sustained product, is this convention apply for other products as well or this product in particular?**

  It is difficult to formulate a product so that a drug concentration in the body is maintained within a narrow range. This will be very evident when we study pharmacokinetics. A large therapeutic range is always preferred, for all types of products.

- **Under what conditions sustained product should administered rectally?**

  Oral immediate release products can often be administered rectally, but oral sustained release products should not be administered rectally because the product is usually expelled before the drug is released. Some suppositories are sustained release but not very many, and the only way to tell is to read the package insert.

- CAP is **cellulose** acetate phthalate. There are other chemical phthalates besides **cellulose** acetate and they are all used in pharmaceutics for the same purpose=enteric coating.

- Question is not clear. I think this is referring to the fact that in order to formulate a drug into a sustained release product, it is necessary that the drug be absorbed well throughout the GI tract.

- Sucrose is a direct compression binder, if it has been formulated as granules first. As a powder it would be a filler, and as a syrup, it would be used in sugar coating.

- Glidents are not lubricants, but good lubricants act as glidents. A glident helps granules flow well.

- Stearates are both lubricants and anti-adherents.

- See FAQ on web about starch (includes hydrophilic polymers as a class) in terms of absorbents.

- "Capping" occurs because air is entrapped and when pressure is released, the air expands and pops off the top of the tablet. With good granules, capping does not occur.

- For most drugs, the maximum intensity of response occurs at the same time as the peak drug concentration in the blood. This is because the drug concentration in the blood is in equilibrium with the drug at the receptor site, and the intensity of response is dependent upon the amount of drug at the receptor site.

- Carrying capacity refers to the amount of drug that a direct compression binder can "carry" into a good tablet. Thus, a carrying capacity of 40% means that the tablet can contain 40% drug and 60% excipients, which are mostly the direct compression binder.

- Lactose is not as inert as MCC because lactose is absorbed and metabolized, and some people are sensitive to lactose, i.e., have a lactose intolerance.

- Ethylycellulose is a good coating material and the reason it is good is because it is insoluble so it remains intact on a bead or tablet and controls the drug release. If the ethylcellulose were soluble, then it would dissolve and lose the ability to control drug release.

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28 January 2002
PHAR 733 Introduction of Pharmaceutical Dosage Forms
College of Pharmacy at Oregon State University
Comments to: Rosita.Rodriguez@orst.edu

Featured Excipient - USP/NF CASPSULE AND TABLET DILUTENS

Calcium Carbonate, USP

Calcium carbonate (CaCO3, MW 100.09, precipitated calcium carbonate, precipitated carbonate of lime, precipitated chalk) occurs as a fine, white, odorless, tasteless, **microcrystalline** powder that is stable in air. It is practically insoluble in water and insoluble in alcohol. It dissolves with effervescence in 1 N acetic acid, in 3 N hydrochloric acid and in 2 N nitric acid. When used in tablets containing aspirin, traces of iron may cause discoloration, which may be overcome by using a suitable chelating agent.[1,2]

Dibasic Calcium Phosphate, USP

Dibasic calcium phosphate (CaHPO4, MW 136.06) is anhydrous or contains two molecules of water of hydration. It occurs as a white, odorless, tasteless powder that is stable in air. It is practically insoluble in water, insoluble in alcohol and soluble in 3 N hydrochloric acid and 2 N nitric acid. They are both used as excipients and as a source of calcium in nutritional supplements. It should not be used to formulate tetracycline antibiotics and has been reported to be incompatible with indomethacin, aspirin, aspartame, ampicillin, cephalexin and erythromycin. The coarse grade material has good flow properties, but is abrasive and requires a lubricant when used for tableting. The surface of the milled particles is alkaline and should not be used with drugs that are sensitive to alkaline pH. The surface of the unmilled particles may be acidic. It is widely used in oral pharmaceutical products, food products and toothpastes. It should be labeled to indicate whether it is anhydrous or the dihydrate.[1,3]

Dibasic Calcium Phosphate Dihydrate, USP

Dibasic calcium phosphate dihydrate (CAHPO4.2H2O, MW 172.09) is nonhygroscopic but can lose its water of crystallization below 100 C.[1,4]

Tribasic Calcium Phosphate, NF

Tribasic calcium phosphate [Ca5(OH)(PO4)3, MW 502.31, hydroxyapatite, precipitated calcium phosphate] is not a defined entity but consists of a variable mixture of calcium phosphates having the approximate composition of 10

CaO.3P2O5.H2O [corresponding to a molecular formula of Ca5(OH)(PO4)3 or Ca10(OH)2(PO4)6] containing between 34 and 40% of calcium. It occurs as a white, odorless, tasteless powder that is stable in air. It is practically insoluble in water, insoluble in alcohol, and readily soluble in 3 N hydrochloric acid and 2 N nitric acid. It is used as an anticaking agent, glidant and tablet/capsule diluent. Calcium salts are incompatible with tetracycline antibiotics. Tribasic calcium phosphate is also incompatible with tocopheryl acetate (but not tocopheryl succinate). It can influence the absorption of vitamin D and may form sparingly soluble phosphates with hormones.[1,5]

Calcium Sulfate, NF

Calcium sulfate is either anhydrous (CaSO4, MW 136.14, anhydrous gypsum, anhydrous sulfate of lime) or contains two molecules of water of hydration (CaSO4.2H2O, MW 172.17, alabaster, gypsum, light spar, mineral white, native calcium sulfate, precipitated calcium sulfate, satinite, satin spar, selenite, terra alba). It occurs as a fine, white to slightly yellow-white, odorless powder. It is slightly soluble in water (1 in 375) and soluble in 3 N hydrochloric acid. It should be labeled to indicate whether it is anhydrous or dihydrate. It also occurs as a hemihydrate form used in the preparation of plaster of paris bandages; this form should NOT be used in the preparation of tablets or capsules. Calcium sulfate anhydrous is hygroscopic and the uptake of water can result; it is not recommended for the formulation of tablets, capsules or powders for oral administration. The dihydrate form is used in oral preparations.

Calcium salts may be incompatible, in the presence of moisture, with amines, amino acids, peptides and proteins, which may form complexes. Calcium salts will interfere with tetracycline antibiotics. Calcium sulfate would be incompatible with indomethacin, aspirin, aspartame, ampicillin, cephalexin and erythromycin. Calcium sulfate, at high temperatures, may react violently with phosphorus and aluminum powder.[1,6]

Microcrystalline Cellulose, NF

Microcrystalline cellulose [(C6H10O5)n where n ~~ 220, MW ~~36,000] is purified, partially depolymerized **cellulose** prepared by treating alpha **cellulose**, obtained as a pulp from fibrous plant material, with mineral acids. It occurs as a fine, white or almost white powder consisting of free-flowing, nonfibrous particles. It is insoluble in water, dilute acids and most organic solvents. It is practically insoluble in sodium hydroxide solution (1 g in 20 mL). It should be labeled to indicate it's nominal loss on drying, bulk density and degree of polymerization values. It is used as an **adsorbent**, suspending agent, tablet disintegrant and tablet/capsule diluent. It is incompatible with strong oxidizing agents.[1,7]

Powdered Cellulose, NF

Powdered **cellulose** [(C6H10O5)n where n = 500, MW ~~243,000] is derived from a natural polymer, hence it has a variable chain length and variable molecular weight. It is purified, mechanically disintegrated **cellulose** prepared by processing alpha **cellulose**

obtained as a pulp from fibrous plant materials. It occurs as a white or almost white powder that exhibits degrees of fineness ranging from a free-flowing dense powder to a coarse, fluffy, nonflowing material. It is insoluble in water, dilute acids and in nearly all organic solvents. It is slightly soluble in sodium hydroxide solution (1 g in 20 mL). It is used as an **adsorbent**, glidant, suspending agent, tablet disintegrant and tablet/capsule diluent. It has also been used in oily suspension filled capsules to reduce the sedimentation rate of the incorporated powders. It is incompatible with strong oxidizing agents. It should be labeled to indicate the nominal degree of polymerization.[1,8]

Dextrates, NF

Dextrates is a purified mixture of saccharides resulting from the controlled enzymatic hydrolysis of starch. It is either anhydrous or hydrated and contains between 93 and 99% of dextrose equivalent, calculated on the dried basis. It is free-flowing, porous, white, odorless, spherical granules consisting of aggregates of microcrystals. It has a sweet taste and produces a cooling sensation in the mouth. It may be directly compressed into self-binding tablets; it is used in the preparation of chewable, nonchewable, soluble, dispersible and effervescent tablets. Dextrates is freely soluble in water (1 g in 1 mL), insoluble in ethanol, and soluble in dilute acids and alkalies. It should be labeled to state whether it is anhydrous or hydrated. Dextrates are incompatible with oxidizing agents and also may react with substances containing a primary amino group at high temperatures and humidities; the Maillard reaction.[1,9]

Dextrin, NF

Dextrin (British gum, canary dextrin, crystal gum, starch gum, yellow dextrin, white dextrin, [(C6H10O5)n.xH20, MW 162.14--the molecular weight is typically 4,500-85,000 depending upon the number of monomer units] is starch, or partially hydrolyzed starch, modified by heating in a dry state, with or without acids, alkalies or pH control agents. Its source is primarily from corn or potatoes; it has different characteristics depending upon its source and method of preparation. It occurs as a free-flowing, white, yellow or brown powder. It is also defined as a dextrose polymer. Its solubility in water varies but it is usually very soluble; it may contain an insoluble portion. It is incompatible with strong oxidizing agents.[1,10]

Dextrose Excipient, NF

Dextrose excipient is a sugar usually obtained by hydrolysis of starch, containing one molecule of water of hydration. It occurs as colorless crystals or as a white, crystalline or granular powder. It is odorless and sweet-tasting. It is freely soluble in water and very soluble in boiling water. It is slightly soluble in alcohol. It should be labeled to indicate that it is not intended for parenteral use. It may cause browning in tablets containing amines.[1]

Fructose, USP

Fructose (fruit sugar, levulose, C6H12O6, MW 180.16) occurs as colorless crystals or as a white, crystalline odorless powder with a sweet taste. It is freely soluble in water

(1g in 0.3 mL) and soluble in alcohol (1 g in 15 mL). Fructose is incompatible with strong acids or alkalis forming a brown coloration. When in aldehyde form, it can react with amines, amino acids, peptides, and proteins; it may cause browning of tablets containing amines.[1,11]

Kaolin, USP

Kaolin (argilla, bolus alba, china clay, porcelain clay, white bole, hydrated aluminum silicate, Al2O3.2SiO2.2H20) occurs as a soft, white or yellowish white powder or as lumps. It is a naturally occurring mineral, has an earthy or clay-like taste and, when moistened with water, assumes a darker color and develops a marked clay-like odor. It is insoluble in water, cold dilute acids and in solutions of alkali hydroxides. Kaolin is an **adsorbent** and may alter the absorption of orally administered drugs such as amoxicillin, ampicillin, cimetidine, digoxin, lincomycin, phenytoin, and tetracycline.[1,12]

Lactitol, NF

Lactitol (C12H24O11, MW 344.31, lactil, lactite, lactobiosit, lactosit) occurs as the anhydrous, monohydrate (MW 362.34) or the dihydrate (MW 380.35) forms. It is produced by the catalytic hydrogenation of lactose. It is odorless and has a sweet taste (about one-third that of sucrose) imparting a cooling sensation in the mouth; it does not promote dental caries. It is soluble in water (1 g in1.75 mL). It should be labeled to indicate whether it is the monohydrate, the dihydrate or the anhydrous form.[1,13]

Lactose Anhydrous, NF

Lactose anhydrous (C12H22O11, MW 342.3, milk sugar, saccharum lactis) is primarily beta lactose or a mixture of alpha and beta lactose. It occurs as a white or almost white powder that is freely soluble in water (1 g in 5 mL) and practically insoluble in alcohol.

Lactose Monohydrate, NF

Lactose monohydrate (C12H22O11.H2O, MW 360.31) is a natural disaccharide, obtained from milk, which consists of one glucose and one galactose moiety. Lactose monohydrate is widely used as a filler or diluent in tablets, capsules, infant formulas and lyophilized products. It is available in different grades with varying physical properties such as particle size distribution and flow characteristics. The dosage form being prepared dictates the type of lactose to be used. Lactose occurs as a white, free-flowing powder that is freely but slowly soluble in water (1 g in 4.63 mL) and practically insoluble in alcohol; it is odorless and slightly sweet-tasting. It should be labeled to state the particle size distribution and if modified, it should indicate the method of modification. Lactose may undergo a Maillard-type condensation reaction with compounds containing a primary amine group to form brownish colored products; this is accelerated in alkaline environments. Lactose is listed as incompatible with amino acids, aminophylline and amphetamines.[1,14]

Mannitol, USP

Mannitol (C6H14O6, MW 182.17, manna sugar, mannite) occurs as a white, crystalline powder or as free-flowing granules. It is odorless and has a sweet taste. It is freely soluble in water (1 g in 5.5 mL), soluble in alkaline solutions and very slightly soluble in alcohol (1 g in 83 mL). It is commonly used in direct-compression tablets and as an excipient in the manufacture of chewable tablets due to its negative heat of solution and the resulting cooling effect. There are no listed incompatibilities of mannitol when in the dry state.[1,15]

Sorbitol, NF

Sorbitol (C6H14O6, MW 182.17, d-Glucitol) occurs as white, hygroscopic powder, granules or flakes, with a sweet taste. It is very soluble in water (1 g in 0.45 mL) and slightly soluble in alcohol (1:25). It is used as a humectant, plasticizer, sweetening agent, and tablet and capsule diluent. There are no listed incompatibilities of sorbitol in the dry state.[1,16]

Starch, NF

Starch [(C6H10O5)n where n = 300-1000] consists of the granules separated from the mature grain of corn, wheat, tubers or tapioca. Starches obtained from different botanical sources may not have identical properties with respect to their use for specific pharmaceutical purposes, therefore, types of starch should not be interchanged unless performance equivalency has been demonstrated. As an example, corn starch contains about 27% amylose, potato starch about 22% and tapioca starch about 17%; these differences provide for different physical properties. Starch generally occurs as irregular, angular, white masses or as a fine powder. It is odorless and has a slight, characteristic taste. It is insoluble in cold water and in alcohol. It should be labeled to indicate the botanical source from which it was derived. Corn starch is also known as maize starch and tapioca starch is also known as cassava starch. Starch has no listed incompatibilities.[1,17]

Pregelatinized Starch, NF

Pregelatinized starch [(C6H10O5)n, where n = 300-1000)] is starch that has been chemically and/or mechanically processed to rupture all or part of the granules in the presence of water and subsequently dried. Pregelatinized starch occurs as a moderately coarse to fine, white to off-white powder. It is odorless and has a slight, characteristic taste. It is slightly soluble to soluble in cold water and is insoluble in alcohol. It has no listed incompatibilities.[1,18]

Sucrose, NF

Sucrose (C12H22O11, MW 342.30, beet sugar, cane sugar, refined sugar, saccharose, sugar) is obtained from various sources. It occurs as a white crystalline powder or as lustrous, dry, colorless or white crystals. It is very soluble in water (1 g in 0.5 mL), slightly soluble in alcohol (1 in 170) and practically insoluble in dehydrated alcohol. Sucrose may be contaminated with traces of heavy metals that can lead to an incompatibility with active ingredients as ascorbic acid. It also may contain sulfite from the refining process.[1,19]

Compressible Sugar, NF

Compressible sugar may contain starch, malto-dextrin or invert sugar and may contain a suitable lubricant; it contains between 95 and 98% sucrose. It is used in the preparation of direct compression chewable tablets. It occurs as a practically white, crystalline, odorless powder with a sweet taste; it is stable in air. The sucrose portion of compressible sugar is very soluble in water. It is incompatible with dilute acids and can react with alkaline earth hydroxides to form sucrates.[1,20]

Confectioner's Sugar, NF

Confectioner's sugar is sucrose ground with corn starch to a fine powder; it contains not less than 95% sucrose. It has been used in pharmaceutical formulations when a rapidly dissolving form of sugar is needed for flavoring or sweetening. It occurs as a fine, white, odorless powder with a sweet taste; it is stable in air. The sucrose portion of confectioner's sugar is soluble in cold water. Confectioner's sugar is freely soluble in boiling water. It is incompatible with dilute acids and can react with alkaline earth hydroxides to form sucrates.[1,21]

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